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No.

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In the Supreme Court of the United States

OCTOBER TERM, 1994

DONNA E. SHALALA, SECRETARY OF HEALTH
AND HUMAN SERVICES, PETITIONER

v.

MARGARET WHITECOTTON, ET AL.

**PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

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QUESTIONS PRESENTED

1. Whether, under the National Childhood Vaccine Injury Act, 42 U.S.C. 300aa-11(c), proof that a manifestation of a brain injury occurred shortly after administration of a vaccine creates a presumption that the vaccine caused the "onset" of the injury, when the injury had already manifested itself prior to administration of the vaccine.

2. Whether, if such a presumption of causation is created, the government may rebut it by showing that an identified preexisting condition caused the injury, even though the specific cause of that condition is unknown.

II

PARTIES TO THE PROCEEDINGS

The petitioner is Donna E. Shalala, the Secretary of Health and Human Services. The respondents are Margaret, Kay and Michael Whitecotton.

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The Solicitor General, on behalf of Donna E. Shalala, the Secretary of Health and Human Services, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-9a) is reported at 17 F.3d 374. The opinion of the United States Claims Court (now the Court of Federal Claims) (App., *infra*, 10a-23a) and the decision of the Special Master (App., *infra*, 24a-43a) are unreported.

JURISDICTION

The judgment of the court of appeals was entered on February 15, 1994. A petition for rehearing was

(1)

denied on April 29, 1994. App., *infra*, 44a-45a. By order dated July 19, 1994, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including August 27, 1994 (a Saturday). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

The National Childhood Vaccine Injury Act of 1986, 42 U.S.C. 300aa-1 *et seq.* (1988 & Supp. IV 1992), provides in pertinent part:

§ 300aa-11. Petitions for compensation

* * * *

(c) Petition content

A petition for compensation under the Program for a vaccine-related injury or death shall contain—

(1) except as provided in paragraph (3), an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died—

* * * *

(C)(i) sustained, or had significantly aggravated, any illness, disability, injury or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administra-

tion set forth in the Vaccine Table,
* * *

* * * *

§ 300aa-13(a)(1). Determination of eligibility and compensation

(a) General rule

(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

(2) For purposes of paragraph (1), the term “factors unrelated to the administration of the vaccine”—

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumented cause, factor, injury, illness, or condition, * * *

* * * *

§ 300aa-14(a). Vaccine Injury Table

(a) Initial table

The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and

deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program * * *.

(b) Qualifications and aids to interpretation

* * * *

(3)(A) The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain.
* * *

* * * *

§ 300aa-33. Definitions

* * * *

(4) The term "significant aggravation" means any change for the worse in a preexisting condition which results in markedly greater disability, pain or illness accompanied by substantial deterioration of health.

STATEMENT

1. In 1986, Congress enacted the National Childhood Vaccine Injury Act (Vaccine Act). Pub. L. No. 99-660, Tit. III, 100 Stat. 3755, codified as amended at 42 U.S.C. 300aa-1 *et seq.* (1988 & Supp. IV 1992). Part 1 of the Act directs the Secretary of Health and Human Services to establish a National Vaccine Program designed "to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C. 300aa-1; see 42 U.S.C. 300aa-1 to 300aa-6 (1988 & Supp. IV 1992). Part 2 of the Act, at issue here, establishes a National Vaccine Injury Compensation Program (Compensation

Program), administered by the Secretary, "under which compensation may be paid for a vaccine-related injury or death." 42 U.S.C. 300aa-10(a); see 42 U.S.C. 300aa-10 to 300aa-34 (1988 & Supp. IV 1992).

A proceeding under the Compensation Program is initiated by the filing of a petition in the Court of Federal Claims. 42 U.S.C. 300aa-11(a)(1) (Supp. IV 1992). The claimant may establish entitlement to compensation in either of two ways. Under the first method, the claimant must prove by a preponderance of the evidence that he or she sustained (or had significantly aggravated) any illness, disability, injury, or condition that was caused by the administration of a covered vaccine. See 42 U.S.C. 300aa-11(c)(1)(C)(ii). Under the second method, which respondents have pursued, the claimant may rely on the Vaccine Injury Table (Table), which in effect establishes a rebuttable presumption of causation in certain circumstances.

The Vaccine Injury Table identifies vaccines covered by the Act and lists particular injuries, disabilities, illnesses, and conditions after each vaccine. The Table then specifies for each such injury, disability, illness, or condition a "[t]ime period for first symptom or manifestation of onset or of significant aggravation after vaccine administration." See 42 U.S.C. 300aa-14(a) (1988 & Supp. IV 1992) (setting forth the Table). The claimant is entitled to the rebuttable presumption of causation created by the Table if the court finds on the record as a whole that the claimant has shown by a preponderance of the evidence that he or she sustained (or had significantly aggravated) an illness, disability, injury, or condition set forth in the Table, and

that the "first symptom or manifestation of [its] onset or of [its] significant aggravation" occurred within the time period after vaccine administration set forth in the Table. 42 U.S.C. 300aa-11(c)(1)(C)(i); see 42 U.S.C. 300aa-13(a)(1)(A). The Secretary may rebut that presumption (and defeat the claim for compensation) by showing by a preponderance of the evidence that the illness, disability, injury, or condition "is due to factors unrelated to the administration of the vaccine described in the petition." 42 U.S.C. 300aa-13(a)(1)(B). The term "factors unrelated to the administration of the vaccine" does not, however, "include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition." 42 U.S.C. 300aa-13(a)(2)(A).

Cases under the Vaccine Act are adjudicated in the first instance by a special master. 42 U.S.C. 300aa-12(d)(3) (Supp. IV 1992). On motion by a party, the Court of Federal Claims will review the special master's decision. That court may either uphold the decision, or "set aside any findings of fact or conclusion of law * * * found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law." 42 U.S.C. 300aa-12(e)(2)(B) (Supp. IV 1992). The decision of the Court of Federal Claims is subject to review in the United States Court of Appeals for the Federal Circuit. 42 U.S.C. 300aa-12(f) (Supp. IV 1992).

2. Respondent Margaret (Maggie) Whitecotton was born on April 22, 1975, with a condition known as microcephaly. App., *infra*, 11a, 33a-34a. Microcephaly is most commonly defined as a head size smaller than two standard deviations below the norm for a child of the same age and sex. *Id.* at 32a. Maggie was borderline microcephalic at birth and

clearly microcephalic before she received her third diphtheria-pertussis-tetanus (DPT) vaccination at about four months of age. *Id.* at 32a-34a.

On August 19, 1975, the day after Maggie received her third DPT vaccine, she suffered a series of seizures. App., *infra*, 2a. Maggie was hospitalized, but she was discharged three days later after a neurological examination indicated that her condition was normal. *Id.* at 40a. In discussing the seizures, the discharge summary expressed one treating physician's opinion that "children with microcephaly and some brain damage [are] unusually susceptible to this vaccine." *Id.* at 30a. Maggie had several seizures over the next five years, but has not had any in recent years. *Id.* at 2a. She now has cerebral palsy and hip and joint problems, and she cannot communicate verbally. *Ibid.*

On August 2, 1990, Maggie's parents, who are also respondents herein, applied for compensation under the Vaccine Act. App., *infra*, 2a. They alleged that Maggie had suffered an "encephalopathy" as a result of her third DPT vaccination. *Ibid.* An encephalopathy is defined by the Vaccine Act as "any significant acquired abnormality of, or injury to, or impairment of function of the brain." 42 U.S.C. 300aa-14(b)(3)(A). To trigger the presumption of causation under the Table, a symptom or manifestation of the onset or significant aggravation of an encephalopathy must occur within three days after administration of the DPT vaccine. 42 U.S.C. 300aa-14(a) (1988 & Supp. IV 1992). Maggie's parents alleged that her post-vaccine seizures were such a manifestation.

3. The special master denied compensation. App. *infra*, 24a-43a. The special master was persuaded by the evidence concerning Maggie's head size since birth and the testimony of neurologists that "Maggie had suffered an encephalopathy sometime prior to the administration of the DPT vaccine on August 18, 1975." *Id.* at 33a; see also *id.* at 34a ("Whether the injury occurred prior to birth or thereafter, the preponderance of the evidence indicates that Maggie was already encephalopathic prior to August 18, 1975."). The special master therefore concluded that "[h]er original encephalopathy was not a Table injury which followed the August 18 DPT shot." *Id.* at 34a.

The special master also concluded that the seizures that had occurred within the three-day statutory period after administration of the vaccine did not significantly aggravate Maggie's preexisting encephalopathy. App., *infra*, 42a-43a. The special master found that the DPT vaccine "may have caused a temporary encephalopathy evidenced by transient seizure activity, but the seizures did not continue and there was no dramatic turn for the worse in her condition indicating a permanent aggravation of her brain disorder." *Id.* at 42a. Rather, the special master explained, as Maggie "matured neurologically, the complications of whatever caused her microcephaly gradually manifested themselves, just as they do in a typical case involving congenital brain damage." *Ibid.* Accordingly, the special master found "no basis for implicating the vaccine as the cause of any aspect of her present condition." *Id.* at 42a-43a.¹

¹ The conclusions discussed in the text were also embodied in the special master's formal findings of fact, which recited that Maggie was "born * * * with a brain disorder evidenced

4. The United States Claims Court (now the Court of Federal Claims) overruled respondents' objections to the special master's decision and entered judgment for the Secretary. App., *infra*, 10a-23a. The court concluded that there was sufficient evidence to support the special master's finding that Maggie was microcephalic before she received her third DPT vaccination, and that her preexisting injury therefore precluded the vaccine from being the cause of the encephalopathy. *Id.* at 19a-21a. The court also concluded that there was sufficient evidence to support the special master's finding that the seizures that occurred within the three-day statutory period after administration of the vaccine were not an indication that the preexisting encephalopathy was significantly aggravated by the vaccine. *Id.* at 23a. As the court viewed the record, "[t]here is simply no evidence that these transient seizures were a sign of permanent brain damage." *Ibid.* Instead, it observed, the evidence indicated "that Maggie's entire clinical history is typical for a person with a condition similar to Maggie's who did not have vaccine complications." *Ibid.*

5. The court of appeals reversed the judgment of the Claims Court and remanded for an award of

by microcephaly which became more pronounced by the age of four months"; that she "suffered transient seizure activity within three days following the administration of the DPT vaccine, the residual effects or complications of which did not continue for six months"; that she "did not suffer a permanent encephalopathy within three days following the said administration of DPT vaccine"; and that "[n]o significant aggravation of Maggie's underlying brain disorder was manifested within three days following the said administration of the DPT vaccine." App. *infra*, 43a.

compensation. App., *infra*, 1a-9a. The court of appeals held that respondents' showing that Maggie had suffered seizures within three days of administration of the vaccine was sufficient to establish a presumption that the vaccine had caused the encephalopathy. *Id.* at 5a-7a. The court reasoned that "the Table language is that the first symptom *after vaccine administration* must occur within Table time, not, as the Secretary argues, that the first of all manifestations must so occur." *Id.* at 5a.

The court of appeals then held that the Secretary could not rely on Maggie's preexisting microcephaly to show that her injury was caused by a "factor unrelated" to the vaccine. App., *infra*, 7a-8a. The court did not disturb the special master's findings that Maggie "was microcephalic before she received the suspect vaccine," and that her "microcephaly marked [her] as a child likely to experience developmental problems." *Id.* at 8a. Moreover, the court acknowledged that "[l]ogically, these findings point to some preexisting condition, and not the vaccine, as the source of Maggie's injury." *Ibid.* Nonetheless, the court held that Maggie's microcephaly was not a "factor unrelated" to the administration of the vaccine within the meaning of the Vaccine Act. *Id.* at 6a. Relying on its decision in *Koston v. Secretary, Dep't of Health & Human Servs.*, 974 F.2d 157, 160-161 (1992), the court concluded that Maggie's microcephaly was an "idiopathic" factor because, although it was preexisting, its specific cause could not be identified. App., *infra*, 7a-8a.²

² The Secretary's petition for rehearing, with suggestion of rehearing en banc, was denied, with one judge dissenting. App., *infra*, 44a-45a.

REASONS FOR GRANTING THE PETITION

The court of appeals has interpreted the National Childhood Vaccine Injury Act of 1986 to require compensation in circumstances in which logic compels the conclusion that a child's condition was not caused by a vaccine. That interpretation is demonstrably at odds with the text of the Act and threatens the fiscal integrity of the compensation program. Because the Federal Circuit is the only court of appeals with authority to review Vaccine Act cases, review by this Court is necessary to correct that circuit's serious misreading of the Act and to restore the integrity of the National Vaccine Injury Compensation Program.

1. The court of appeals has held that there is a statutory presumption that a vaccine caused the onset of an injury or condition if a manifestation of the injury or condition happens to occur within a specified time after administration of the vaccine, even though that injury or condition already had manifested itself prior to administration of the vaccine. An example is useful in illustrating just how extraordinary that holding is. If a child had experienced seizures regularly from birth, a showing that the child happened to experience an identical seizure within the statutory period after administration of the vaccine would create a presumption that the vaccine had caused the onset of a brain impairment. If the court of appeals is correct, Congress has mandated a presumption of causation in circumstances in which the only available indications are that the vaccine did *not* cause the injury or condition.

A presumption of that kind would make no sense, but its adverse consequences for the integrity of the Compensation Program might be mitigated if the

Secretary could rebut the presumption by showing that the child's current injury or disability was caused by a preexisting condition. The court of appeals has further held, however, that the Secretary cannot rebut the presumption by tying the injury or disability to a preexisting condition, unless the Secretary can also identify the specific cause of that preexisting condition—something the Secretary will be unable to do in many cases. For example, even if the Secretary could prove that the child had only a partial brain at birth and that such a condition invariably results in the kind of injury or disability from which the child suffers, the presumption would not be rebutted unless the Secretary were able to identify what had caused the child to have a partial brain. Thus, under the court of appeals' decision, compensation is now required in Vaccine Act cases in circumstances in which the evidence logically compels the conclusion that a known preexisting condition, and not the vaccine, caused the child's current injury or disability.

The court understood that its decision would have that effect. The court expressly acknowledged that because Maggie was microcephalic before administration of the vaccine—and that because Maggie's microcephaly marked her as someone likely to experience developmental problems—it was logical to conclude that a preexisting condition and not the vaccine had caused her injury. App., *infra*, 8a. The court concluded, however, that Congress had mandated compensation anyway. *Id.* at 9a.

2. a. The illogical conclusion reached by the court of appeals is demonstrably at odds with the text of the Vaccine Act. Under 42 U.S.C. 300aa-11(c)(1)(C)(i), a presumption of causation exists when a

claimant shows by a preponderance of the evidence that he or she—

sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with [a specified] vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table.

See 42 U.S.C. 300aa-13(a)(1)(A). That statutory language creates a presumption in two kinds of cases: those in which the claimant shows that he or she first began to suffer from an injury or condition after administration of the vaccine ("onset" cases), and those in which the claimant shows that he or she suffered from a Table injury or condition before receiving the vaccine, but that it markedly worsened after that time ("significant aggravation" cases). In this case, the "first" manifestation of the "onset" of Maggie's brain injury or condition was her preexisting microcephaly. The plain language of the Act therefore makes clear that respondents could not benefit from a statutory presumption of causation absent proof that a manifestation of a "significant aggravation" of Maggie's preexisting brain injury or condition occurred in the statutory three-day period—a showing that respondents failed to make.

The court of appeals was of the view that the statutory phrase "first symptom or manifestation of the onset" means that a claimant is entitled to a presumption of causation as long as *any* symptom or manifestation of an underlying injury or condition occurred within the statutory period. App., *infra*, 5a-

7a. That interpretation cannot be reconciled with the plain meaning of the statutory text and therefore must be rejected. *Connecticut Nat'l Bank v. Germain*, 112 S. Ct. 1146, 1149 (1992). The term "first" means "before all others," and the term "onset" means "a beginning or start." *The Random House Dictionary of the English Language* 723, 1354 (1987). When an injury or condition has manifested itself prior to administration of the vaccine, a manifestation after administration cannot be the "first." And when an injury or condition had its start before administration of the vaccine, any manifestation that occurs after that time cannot be a manifestation of the "onset" of the injury or condition. Simply put, the phrase "first symptom or manifestation of the onset" does not mean merely a *further* symptom or manifestation of a *preexisting* injury.

The court of appeals' interpretation is also flawed because it fails to give any meaning to the statutory text creating a presumption of causation when a pre-existing condition was significantly aggravated after the administration of a vaccine. See *United States v. Nordic Village, Inc.*, 112 S. Ct. 1011, 1015 (1992) ("the settled rule [is] that a statute must, if possible, be construed in such fashion that every word has some operative effect"). If, as the court of appeals concluded, a presumption of causation arises whenever any symptom occurs within the statutory period, there would never be a need for a claimant to establish a significant aggravation of a preexisting injury. The "significant aggravation" presumption makes sense only if a finding of a pre-vaccine condition precludes the claimant from establishing a post-vaccine "onset." Thus, the necessary implication of the "significant aggravation" presumption is that there can-

not be a presumption of causation when a condition that manifested itself before administration of the vaccine did not get markedly worse afterwards. See 42 U.S.C. 300aa-33(4) (defining "significant aggravation" as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health").

The legislative history of the Vaccine Act confirms that obvious point. The House Report explains that the Act does not "include compensation for conditions which might legitimately be described as pre-existing (*e.g.*, a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), but is meant to encompass serious deterioration (*e.g.* a child with monthly seizures who, after vaccination, has seizures on a daily basis)." H.R. Rep. No. 908, 99th Cong., 2d Sess. Pt. 1, at 14-16 (1986).

b. The court of appeals purported to find support for its interpretation of the statutory presumption in two other provisions of the Act. The court, however, misperceived the effect of each.

First, the court of appeals deemed it significant that Congress provided that a residual seizure disorder could be found if the claimant "did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved." 42 U.S.C. 300aa-14(b)(2). Because Congress included no such limitation with respect to an encephalopathy, the court reasoned, it must not have intended to require claimants to show that there was no preexisting symptom or manifestation of that injury or condition. App., *infra*, 5a-6a. The special

provision addressing seizure disorders was necessary, however, because seizures accompanied by high fevers may not be symptomatic of a seizure disorder. To avoid any uncertainty about whether the existence of pre-vaccine seizures accompanied by high fevers would preclude a showing of post-vaccine onset, Congress made clear that they would not. Thus, the provision does not indicate that Congress required claimants to show the absence of preexisting symptoms in residual seizure disorder cases, but not in others. Instead, it clarifies how the general statutory requirement—that a claimant must show that a manifestation that occurred within the statutory period was the first such manifestation—should be applied in the special circumstances of alleged residual seizure disorders.

The court of appeals also attributed significance to the provision in the Act that permits a prima facie case to be defeated upon proof that “infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances” caused the child’s injury or condition. 42 U.S.C. 300aa-13(a)(2)(B). According to the court, “[i]t would make no sense to allow proof by the Secretary of birth trauma as a factor unrelated if the petitioner were required to prove that no such preexisting injury occurred as an element of the Table case.” App., *infra*, 6a. The “factors unrelated” provision, however, serves the distinct purpose of permitting the Secretary to rebut a prima facie case of causation by showing that, even though there was no preexisting symptom or manifestation of the injury or condition, it nonetheless was caused by a preexisting factor, such as birth trauma. That provision is therefore entirely compatible with the requirement that the claimant must

show that a post-vaccine manifestation of an injury was the “first” such manifestation in order to establish a presumption of post-vaccine “onset.”

3. The court of appeals’ further holding that the Secretary could not rely on Maggie’s preexisting microcephaly to rebut a prima facie case of causation likewise rests on a serious error of statutory interpretation. The Act precludes the Secretary from relying on an “idiopathic” factor to rebut a prima facie case, and medical dictionaries uniformly define “idiopathic” as “of unknown cause.” *International Dictionary of Medicine and Biology* 1398 (1986); *Stedman’s Medical Dictionary* 762 (25th ed. 1990); *Dorland’s Illustrated Medical Dictionary* 815 (27th ed. 1988); *American Medical Association Encyclopedia of Medicine* 566 (1989). The Secretary therefore cannot attempt to defeat a prima facie case by relying on a statement from an expert such as “I have no idea what caused the injury, but it could not have been the vaccine.” That statutory protection for the claimant is important. There is a considerable body of medical opinion that serious adverse neurological events following vaccinations are exceedingly rare. Because the Act precludes reliance on “idiopathic” or “unknown” factors to rebut a prima facie case, the Secretary could not rely on that body of medical opinion alone to rebut a prima facie case. The Secretary instead must point to some identifiable condition as an explanation for a claimant’s injuries. When the Secretary is unable to do that, the Act requires that the claimant receive the benefit of the doubt on the issue of causation, even though it may be unlikely that the vaccine actually caused the injury.

Here, however, the Secretary *did* identify a specific preexisting condition—microcephaly—to explain respondent's brain injury. That condition predictably leads to retardation, and Maggie had that condition from birth. As the court of appeals recognized, that evidence logically pointed to a preexisting condition, rather than the vaccine, as the cause of her brain injury. App., *infra*, 8a.

The court of appeals nevertheless concluded that the Secretary was relying on an "idiopathic" factor because the Secretary could not in turn identify the cause of Maggie's preexisting microcephaly. App., *infra*, 7a-8a. The court of appeals took the requirement that an unrelated factor must be non-idiopathic one step further back than Congress intended. The Act gives the claimant the benefit of the doubt in cases in which the Secretary cannot point to any identified condition that justifies elimination of the vaccine as the cause of the injury. It does not require compensation in circumstances in which the Secretary can point to a specific condition that logically eliminates the vaccine as the cause of the child's current injury or disability, simply because the cause of that specific condition is unknown.

The legislative history supports that reading of the statutory text. The House Report states that unrelated factors cannot include "speculative or hypothetical matters or explanations." H.R. Rep. No. 908, 99th Cong., 2d Sess. Pt. 1, at 18 (1986). It makes clear, however, that the Secretary may rebut the presumption of causation by relying on "other, defined illnesses or factors." *Ibid.* The court of appeals' contrary view makes no sense. Congress could not have intended to permit compensation in circumstances in which the evidence clearly shows that a

preexisting condition, and not the vaccine, caused the child's injury or disability.

4. The court of appeals' decision will affect hundreds of pending and future Vaccine Act cases. The average cost of compensating a child with severe brain injuries is approximately \$1 million. The court of appeals' decision will therefore have an enormous financial impact on the compensation program.

Most immediately, the decision threatens the fiscal integrity of the program for funding retrospective cases, i.e., those cases based on vaccines administered before October 1, 1988. See 42 U.S.C. 300aa-15(j) (1988 & Supp. IV 1992) and 300aa-16(a)(1) (1988 & Supp. IV 1992). In the past, the annual appropriation for retrospective cases (now funded at \$110 million per year³) has been routinely exhausted. After reviewing the medical records in cases that are likely to be resolved in the next two years, the Secretary has estimated that if allowed to stand, the legal standards established in this case will result in more than \$20 million per year in additional compensation being awarded in retrospective cases alone. Such awards could lead to a chronic underfunding of that program. An unfortunate consequence would be that persons who deserve compensation under the Act would have to stand in line behind those who do not.

Moreover, the decision's impact is not limited to retrospective cases. The Secretary expects between 100 and 200 new Vaccine Act cases to be filed each year for the foreseeable future. With the addition of new covered vaccines (see 42 U.S.C. 300aa-14(c)), the number of cases could climb even higher. The

³ See 42 U.S.C. 300aa-15(j) (Supp. IV 1992), as amended by Pub. L. No. 103-66, Tit. XIII, § 13632(b), 107 Stat. 646.

court of appeals' decision therefore could readily require in excess of \$200 million in additional compensation over the next ten years.

The decision is already affecting the adjudication of Vaccine Act cases. For example, in *Cepeda v. Secretary of the Dep't of Health and Human Servs.*, No. 90-2664V (Fed. Cl. July 12, 1994), the special master granted compensation in a case in which the Secretary had claimed that post-vaccine symptoms were caused by a preexisting neurological disorder. The special master concluded that the decision in this case had caused a "dramatic change" in the law governing Vaccine Act cases. Slip op. 2. She specifically noted that the court's decision meant that onset claims and significant aggravation claims "are now identical," and that significant aggravation "need no longer be referenced in the resolution of any Table cases." *Id.* at 5. The special master also observed that the court's decision had altered the previous understanding that the presumption of causation could be rebutted "without the need to establish a particular etiology for a preexisting condition." *Ibid.* The special master viewed the decision in this case as creating a "conundrum," because it requires compensation even when "there is no possible sense in which a condition can be attributed to the vaccine." *Ibid.*; see also *Skinner v. Secretary of Health & Human Servs.*, No. 90-1051V (Fed. Cl. May 31, 1994) (compensation awarded in light of *White-cotton*).

The Federal Circuit has exclusive jurisdiction over appeals in Vaccine Act cases. Thus, unless reviewed by this Court, the Federal Circuit's decision in this case will be the last word on the issues presented here. Because the decision badly misreads the Vac-

cine Act and will have a serious adverse impact on the integrity and financing of the Compensation Program, review by this Court is warranted.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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AUGUST 1994

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

92-5083, 93-5101

MARGARET WHITECOTTON, by her
next friends, KAY WHITECOTTON and
MICHAEL WHITECOTTON, PETITIONERS-APPELLANTS

v.

SECRETARY OF DEPARTMENT OF HEALTH AND
HUMAN SERVICES, RESPONDENT-APPELLEE

Decided: February 15, 1994

Before: NEWMAN, MAYER, and CLEVINGER, Circuit
Judges.

MAYER, Circuit Judge.

Kay and Michael Whitecotton appeal the judgment of the United States Court of Federal Claims,¹ No. 90-692V (Jan. 14, 1992), upholding the special master's denial of their petition under the National Childhood Vaccine Injury Act of 1986. The Whitecottons also appeal the January 7, 1993, order of the Court

¹ The United States Claims Court was renamed the Court of Federal Claims on October 29, 1992, during the course of proceedings in this case before that court. Federal Courts Administration Act of 1992, Pub. L. No. 102-572, § 902(a), 106 Stat. 4506, 4516. For clarity, we use the court's present name.

of Federal Claims denying their motion for relief based on newly discovered evidence. We reverse and remand.

Background

Margaret Whitecotton (Maggie) was born without complications on April 22, 1975. Maggie was a small child—her head circumference at birth was 12.5 inches, or 32 centimeters, placing her in the second percentile on a standard growth chart. Although she might be considered microcephalic based on this measurement, Maggie was healthy, developmentally and physically, until she received her third diphtheria-pertussis-tetanus (DPT) vaccination on August 18, 1975. Maggie's mother took her to the emergency room that evening, after she allegedly saw the child suffer a series of seizures. The treating physician saw no evidence of seizures and discharged Maggie that same night. The next day, Maggie's mother took her to see the family doctor. That doctor saw Maggie experience a series of clonic seizures.

Although Maggie suffered occasional seizures over the next five years, she has suffered none in recent years. She is, however, mentally and physically disabled. She has cerebral palsy, has hip and joint problems, and cannot communicate verbally.

On August 2, 1990, Maggie's parents, as her legal representatives, applied for compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 to 300aa-34 (1988 & Supp. III 1991). They asserted that Maggie suffered a compensable encephalopathy as a result of the August 18 vaccination. The Secretary of Health and Human Services responded that Maggie's condition arose instead from a chronic organic brain syndrome that

preexisted the vaccination, and that, therefore, she deserved no compensation under the Act.

On August 16, 1991, the special master denied compensation, finding that Maggie was born with a brain disorder that was responsible for her present disabilities. The Whitecottons sought review of the decision in the Court of Federal Claims, which affirmed the decision of the special master.

On March 27, 1992, the Whitecottons filed an appeal in this court, which stayed the proceedings pending resolution in the Court of Federal Claims of the Whitecottons' motion for relief from judgment under Rule 60(b)(2). When that motion was denied, the Whitecottons sought review of that denial in this court as well. We now consider the Whitecottons' consolidated appeals.

Discussion

I.

The Whitecottons challenge the interpretation of the Vaccine Act adopted by the special master and affirmed by the Court of Federal Claims, which they argue robbed them of the statutory presumption of causation created by Congress to facilitate recovery for likely vaccine injuries. We review such legal questions de novo. *Hodges v. Secretary, Dep't of Health and Human Services*, 9 F.3d 958, 960 (Fed. Cir. 1993).

The asserted presumption, designed to excuse petitioners from the often onerous burden of proving causation in vaccine cases, attaches whenever the petitioners meet the requirements of the Vaccine Injury Table, 42 U.S.C. § 300aa-14(a). Specifically, petitioners must demonstrate that the injured child re-

ceived a vaccine enumerated in the Table, that the child sustained one of the injuries set forth in the Table within the statutory time period after vaccination, and that the effects of the injury lasted for more than six months, resulting in more than \$1,000 of expenses. *Id.* § 300aa-11(c). If the petitioners fail to meet the Table requirements, they can recover compensation only on the more difficult showing of actual causation. *Id.* § 300aa-11(c)(1)(C)(ii). Once petitioners satisfy their burden of proving presumptive or actual causation by a preponderance of evidence, they are entitled to recover unless the Secretary shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine. *Id.* § 300aa-13(a)(1)(B).

Here, the parties do not dispute that Maggie suffered an encephalopathy that led to her present retardation and cerebral palsy. The only questions are when the encephalopathy occurred and the effect of the date of onset on recovery under the Act.

II.

The Whitecottons say both the special master and the Court of Federal Claims misinterpreted the law, allowing the Secretary to defeat their proven Table injury with a showing of a preexisting brain disorder evidenced by microcephaly, an idiopathic factor unrelated to the vaccine. The Secretary responds that the special master never reached the "factor unrelated" question because the Whitecottons failed to establish their prima facie case when they could not prove that Maggie's August 19, 1975, seizures were the first manifestation of the encephalopathy.

While the special master did conclude that Maggie suffered no Table encephalopathy, we do not agree.

Nowhere does the statute expressly state that proof of a Table encephalopathy includes a showing that the child sustained no injury prior to administration of the vaccine. The Act requires that a petition for compensation include affidavits demonstrating that the first manifestation of the injury occurred within Table time after vaccination, 42 U.S.C. § 300aa-11(c)(1)(C)(i), but the Table itself provides that the statutory period is a "[t]ime period for first symptom or manifestation of onset . . . after vaccine administration." *Id.* § 300aa-14(a). The distinction is significant: the Table language is that the first symptom *after vaccine administration* must occur within Table time, not, as the Secretary argues, that the first of all manifestations must so occur.

Congress could have expressly made the absence of preexisting injury an element of the prima facie case had it so intended. In fact, the qualifications and aids to interpretation of the Table do that for one type of injury, providing that "[a] petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion . . . before the first seizure or convulsion after the administration of the vaccine" *Id.* § 300aa-14(b)(2). Subsequent subsections dealing with encephalopathy place no such limitation on finding Table injury. *See id.* § 300aa-14(b)(3)(A)-(B).²

² Indeed, the Vaccine Act here provides explicitly that

[i]f . . . it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma or metabolic disturbances the encephalopathy *shall not be* considered to be a condition set forth in the table. . . .

42 U.S.C. § 300ee-14(b)(3)(B) (emphasis added). This provision prevents a petitioner from establishing her Table case

Since Congress expressly restricted residual seizure disorders to instances where no seizure occurred before vaccine administration, we assume its failure similarly to limit encephalopathy was intentional. See *Russello v. United States*, 464 U.S. 16, 24 (1983) (“Had Congress intended to restrict § 1963(a)(1) to an interest in an enterprise, it presumably would have done so expressly as it did in the immediately following subsection (a)(2)”; *The Ad Hoc Committee v. United States*, — F.3d — No. 93-1239, slip op. at 6 (Fed. Cir. January 5, 1994).

Moreover, the Act provides that the “factors unrelated” that can defeat a prima facie case may include “infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances” 42 U.S.C. § 300aa-13(a)(2)(B). This section manifestly contemplates that birth trauma, an injury that necessarily must precede administration of any vaccine, can qualify as a factor unrelated to the vaccine and bar recovery. It would make no sense to allow proof by the Secretary of birth trauma as a factor unrelated if the petitioner were required to prove that no such preexisting injury occurred as an element of the Table case.

Because the statute makes sense only if the Secretary bears the burden of proving a preexisting encephalopathy, we decline the Secretary’s argument that the Whitecottons failed to prove their prima facie case. It is undisputed that Maggie suffered an encephalopathy. It is also undisputed that Maggie’s encephalopathy manifested itself in the form of seiz-

if preponderant evidence of record shows that the encephalopathy resulted from one of the four statutorily enumerated causes. The Secretary does not argue that Maggie’s encephalopathy arose from one of these causes.

ures occurring within Table time after vaccination. This suffices to show a Table injury. The Whitecottons deserve the benefit of the Act’s presumed causation.

III.

The special master based his denial of the petition on the evidence of Maggie’s microcephaly. The Secretary offered evidence that microcephalic children are likely to experience developmental difficulties because head growth follows brain development. The special master agreed, reasoning that Maggie’s disabilities arose from a preexisting brain disorder, which might bar recovery as a factor unrelated to the DPT vaccine. However, just as the Act defines what can be a “factor unrelated,” it states what cannot: a factor unrelated to the administration of the vaccine “does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition.” 42 U.S.C. § 300aa-13(a)(2)(A). The Act does not limit its prohibition of idiopathic, or unknown, causes to those demonstrably arising after administration of the suspect vaccine; it forbids the use of any such cause to defeat a petition.

We addressed this same provision in *Koston v. Secretary, Dep’t of Health and Human Services*, 974 F.2d 157, 160-61 (Fed. Cir. 1992), and rejected the notion that a preexisting idiopathic condition can support a finding of alternate causation. In *Koston*, the Secretary first conceded causation of the child’s residual seizure disorder. An independent medical examination revealed that the child suffered from Rett Syndrome, a condition manifested by mental regression and peculiar behavioral symptoms. The Secretary then sought to withdraw the concession of

causation, arguing that because Rett Syndrome was thought to arise from prenatal factors the vaccine could not have been responsible for the child's condition.

We did not accept the Secretary's position because while the medical community believed Rett Syndrome to be genetically determined or derived from a metabolic defect, medical science had not yet firmly identified its cause. Rett Syndrome being an idiopathic condition, an illness with no known cause, it could not support a finding of alternate causation. *Id.* at 161.

We are faced with a similar situation here. The special master found that Maggie was microcephalic before she received the suspect vaccine. He also found that her microcephaly marked Maggie as a child likely to experience developmental problems. Logically, these findings point to some preexisting condition, and not the vaccine, as the source of Maggie's injury. However, the record does not identify this condition. The Secretary's expert testified that microcephaly is often idiopathic, and could point to no specific cause for Maggie's microcephaly. He could only speculate that Maggie suffered a brain injury at some time before she received the vaccine in August 1975. The special master adopted this speculation, stating that as Maggie matured, "the complications of *whatever caused her microcephaly* gradually manifested themselves," and concluded that "there is no basis for implicating the vaccine as the cause of any aspect of her present condition." *Whitcotton v. Secretary, Dep't of Health and Human Services*, No. 90-692V, slip op. at 13 (Cl. Ct. Spec. Mstr. Aug. 16, 1991) (emphasis added). This ignores the statutory presumption.

Congress intended that vaccine awards be made "quickly, easily, and with certainty and generosity." H.R. Rep. No. 908, 99th Cong. 2d Sess. 3 (1986), reprinted in 1986 U.S.C.C.A.N. 6287, 6344. This purpose would not be served by allowing the Secretary to avoid an award by offering "speculative or hypothetical matters or explanations" of alternate causation; under the Act, a Table injury must be presumed vaccine-related unless demonstrated to arise from "other, defined illnesses or factors." *Id.* at 18, 1986 U.S.C.C.A.N. at 6359. This may result in "'compensation to some children whose illness is not, in fact, vaccine related,'" *Koston*, 974 F.2d at 161 (citations omitted), but that is what Congress intended. As in *Koston*, "we have an unknown cause and [symptoms] occurring within three days, the period the Vaccine Injury Table sets for recovery. That is the end of our inquiry" *Id.* The Whitcottons established their prima facie case, and so get the benefit of presumptive causation.

Conclusion

Accordingly, the judgment of the Court of Federal Claims is reversed and the case is remanded to determine compensation.

COSTS

Costs to Kay and Michael Whitcotton.

REVERSED AND REMANDED

APPENDIX B

IN THE UNITED STATES CLAIMS COURT

 No. 90-692-V

MARGARET WHITECOTTON, by her next friends,
KAY WHITECOTTON and MICHAEL WHITECOTTON,
PETITIONER

versus

SECRETARY OF THE DEPARTMENT OF HEALTH
AND HUMAN SERVICES, RESPONDENT

[Filed Jan. 14, 1992]

OPINION and ORDER

TURNER, Judge.

Petitioner seeks review of the special master's August 16, 1991 decision denying compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 - 300aa-34 (1988), *as amended* by several public laws codified in 42 U.S.C.A. §§ 300aa-10 - 300aa-34 (West Supp. 1991) (Vaccine Act), for injuries allegedly suffered as a result of a diphtheria-pertussis-tetanus (DPT) vaccination. For the reasons given below, we conclude that the special

master's decision was not arbitrary or otherwise unlawful, and the decision will be sustained.

I

Margaret (Maggie) Whitecotton was born on April 22, 1975. She was delivered without complications. Maggie received her third DPT vaccination on August 18, 1975. According to her mother, Maggie began to experience seizures (jerking of the arms and eye blinking) later that evening. Her mother took her to an emergency room that night, but the treating physician did not observe any seizure activity. On August 19, 1975, Maggie's mother took Maggie to their family practitioner's office. While Maggie was there, the physician saw her experience a series of clonic seizures. Maggie was hospitalized for the next three days.

At birth, Maggie's head circumference was 12.5 inches. This figures placed her head size in the second percentile on the standard growth chart,¹ where she remained during the first three months of her life. On August 20, 1975, Maggie's head circumference was below the second percentile, and in the months that followed her head size continued to fall further from the normal range.

In February 1976, Maggie's parents hospitalized her for ten days with a possible seizure disorder after she became still, flaccid and pale. She had no seizures while in the hospital, and an EEG taken on the day

¹ The significance of noting that Maggie's head size at birth was in the second percentile is to indicate that statistically 98% of females had larger head circumferences at birth.

after admission was normal. The treating personnel concluded that her upper airway was obstructed by mucus. In January 1977, Maggie developed a fever of about 104 degrees in connection with an upper respiratory infection and was diagnosed with a febrile convulsion. On August 28, 1979, Maggie went limp and her eyes rolled. Her mother took her to an emergency room where she threw up mucus. The hospital admitted her for observation, but she did not have any further problems. Her doctor gave her medication for pneumonitis because a chest x-ray suggested pneumonia in the left lung. It was thought that her initial problem had probably been choking secondary to mucus in her throat. On March 21, 1980, the day after receiving a DT (diphtheria and tetanus) shot, Maggie had a grand mal seizure. Her temperature was recorded at 102 degrees. Maggie has not had any seizures in recent years.

Currently, Maggie has cerebral palsy and mental retardation; she has required surgery for hip and joint problems. She is unable to communicate verbally.

Petitioner claims that she suffered an encephalopathy and a residual seizure disorder, which are both injuries listed in the Vaccine Injury Table, as a result of the August 18, 1975 vaccination. Respondent contends that Maggie's condition is a result of a factor unrelated to the administration of the vaccine. Specifically, respondent claims that Maggie suffered from a preexisting condition called chronic organic brain syndrome. The special master conducted an evidentiary hearing on June 4, 1991 to determine whether petitioner was entitled to compensation

under the Vaccine Act. The special master denied compensation to petitioner for both injuries on August 16, 1991. Petitioner filed a motion for review contending that findings made by the special master were arbitrary, capricious or otherwise unlawful.

II

Section 300aa-11(c)(1) of title 42, U.S.C., lists the matters which a petitioner seeking compensation for a vaccine-related injury must prove. According to section 300aa-11(c)(1), petitioner must prove (1) that the vaccine she received was listed in the Vaccine Injury Table; (2) jurisdictional requirements; (3) that she sustained an injury or had significantly aggravated a preexisting injury; (4) actual or presumed causation; (5) that the residual effects of the injury lasted for more than six months after the administration of the vaccine, resulting in more than \$1,000 in unreimbursable expenses; and (6) that there has been no recovery in a previous civil suit. If each of these requirements is established by a preponderance of the evidence, then the burden shifts to the government to prove by a preponderance of the evidence that the injury was caused by some factor unrelated to the administration of the vaccine. 42 U.S.C.A. § 300aa-13(a)(1).

As section 300aa-11(c)(1)(C) of title 42 indicates, causation may be established in two ways. When an injury listed in the Vaccine Injury Table begins to manifest itself within the time period set forth in the Table for the vaccine in question, then causation is presumed. 42 U.S.C.A. § 300aa-11(c)(1)(C)(i). Alternatively, injuries which are not listed in the Vaccine Injury Table or which do not manifest themselves within the time specified in the

Table may be established by proof of actual causation. 42 U.S.C.A. § 300aa-11(c)(1)(C)(ii). Petitioner pursued this case under the first method.

III

At the June 4, 1990 evidentiary hearing, two expert witnesses, Dr. Ellen Kitts and Dr. Gerald Slater, testified for petitioner. Another expert witness, Dr. Owen Evans, testified for respondent.

Dr. Kitts, a physician specializing in pediatric physical medicine and rehabilitation, testified that her opinion, based upon a reasonable degree of medical certainty, was that Maggie was not born with neurological damage nor did she have brain damage prior to August 18, 1985. Dr. Kitts testified that the DPT vaccination was the sole cause of Maggie's cerebral palsy and mental retardation.

Dr. Slater, a pediatrician and pediatric neurologist, testified that his opinion, based upon a reasonable degree of medical certainty, was that Maggie suffered an injury or an aggravation of an injury as a result of the DPT shot. Nonetheless, Dr. Slater acknowledged the possibility that Maggie was microcephalic prior to the vaccination. He testified that there was no uniformly accepted precise definition of microcephaly (abnormally small head size) but that it was generally thought to be either two or three standard deviations below the mean on the standard growth chart.² Dr. Slater also testified that the seizures occurring after the vaccination were transient and that the subsequent seizure-like occurrences were questionable.

² A standard deviation is a measure of the extent to which the population is disbursed on either side of the mean.

Dr. Evans, a pediatric neurologist, testified that Maggie had congenital organic brain syndrome that was characterized by microcephaly, mental retardation and cerebral palsy. Dr. Evans testified that the definition of microcephaly differed among physicians but that he considered it to be at or below the second percentile on the standard growth chart. Because Maggie was in the second percentile at birth, he considered her to be born with a brain disorder manifested by microcephaly. Dr. Evans testified that his opinion, based upon a reasonable degree of medical certainty, was that the seizures Maggie suffered on August 19, 1975 were related to her congenital organic brain syndrome, not her DPT vaccination.

After hearing the testimony of these experts along with the testimony of Maggie's mother, and considering the clinical history of Maggie, Special Master Baird denied compensation for a residual seizure disorder and an encephalopathy. The special master denied compensation for the residual seizure disorder on the grounds that petitioner did not establish that she suffered from a residual seizure disorder within the meaning of the Vaccine Act or that the residual effects lasted for more than six months following the administration of the vaccine. The special master denied compensation for the encephalopathy on the ground that Maggie had a preexisting brain disorder manifested by microcephaly which accounted for her condition. Moreover, the special master concluded that her preexisting brain disorder was not significantly aggravated by the vaccine.

IV

Section 300aa-12(e)(2) of title 42 provides that upon the filing of a motion for review, the United States Claims Court may review the record and:

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

The Federal Circuit has held that the "arbitrary and capricious" standard in subparagraph (B) is to be "highly deferential" to the special master and that "[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines v. Secretary of HHS*, 940 F.2d 1518, 1528 (Fed. Cir. 1991).

V

The special master found that petitioner was not entitled to compensation for a residual seizure disorder because she did not prove two of the elements listed in section 300aa-11(c)(1) by a preponderance of the evidence. Specifically, the special master found that petitioner failed to establish that she suffered from a residual seizure disorder within the meaning of the Vaccine Injury Table or that the residual effects lasted for more than six months following the administration of the vaccination.

Although the special master determined that Maggie had a series of afebrile clonic seizures on August 19, 1975, he concluded that Maggie did not sustain a residual seizure disorder within the meaning of the Vaccine Act. Petitioner contends that the special master unlawfully required her to prove that she had an additional seizure sometime outside of the six month period following the vaccination. The provision setting forth "[q]ualifications and aids to interpretation" states that:

A petitioner *may* be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if—

. . . .

(B) in the case of [the DPT vaccine], the first seizure or convulsion occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

42 U.S.C.A. § 300aa-14(b)(2) (emphasis added). Plainly, the provision does not require a finding of a residual seizure disorder if its conditions are met. Both the title, "[q]ualifications and aids to interpretation," and the use of the word "may" rather than "shall" in the first sentence suggest that section 14(b)(2) does not compel a finding of a residual seizure disorder if its conditions are met. Thus, the

fact that Maggie's seizures on August 19, 1975 may have been sufficient to support a finding of a residual seizure disorder does not render unlawful the special master's decision to find otherwise.

Moreover, the special master's decision cannot be considered to be arbitrary or capricious. Petitioner's own expert, Dr. Slater, testified that Maggie's seizures on August 19, 1975 were "transient in that she has had no further seizures except for some of those questionable events." Tr. at 191. The statement made by the physicians who treated Maggie in August 1975 also supports the conclusion that her seizures were transient. This statement noted that "the patient's seizures were most likely secondary to the pertussis vaccine" and that "children with microcephaly and some brain damage were unusually susceptible to this vaccine." Ex. F at 1-2. The treating physicians declined to give Maggie any anticonvulsive medications. The special master inferred that the treating physicians considered Maggie's seizures to be transient. Because the special master drew a plausible inference from the discharge statement and based his conclusion on relevant expert testimony, we hold that the conclusion that Maggie did not suffer from a compensable residual seizure disorder was not arbitrary or capricious.

Moreover, the special master's finding that Maggie did not experience the sequela of a residual seizure disorder should be upheld. The clinical history suggests that each of the subsequent seizure-like occurrences resulted from unrelated causes, including upper respiratory infection and pneumonia. Likewise, the expert testimony supports the special master's decision. Dr. Slater testified that the seizures were transient and the subsequent seizure-like occurrences

were of questionable origin. Dr. Evans testified that because the seizures were brief, they did not cause Maggie's subsequent neurological problems. Thus, there is ample evidence in the record to support the decision.

It is true that the findings that Maggie neither sustained a residual seizure disorder nor suffered its residual effects depend on each other to a degree. The special master's theory was that even though Maggie had seizures which were immediately secondary to the DPT vaccination, they were ultimately related to her underlying condition. Thus, because of her underlying neurological condition, he was able to conclude that the subsequent episodes were not primarily related to the DPT vaccination and that the seizures on August 19, 1975 were not sufficient to establish a compensable table injury. Without regard to whether we would have drawn the same inferences or reached the same conclusions, this theory is both lawful and reasonably based on the evidence in the record.³

VI

The special master found that Maggie was microcephalic prior to August 18, 1975 so that she could not have sustained an encephalopathy as a result of the vaccination. The special master reached this conclusion by defining microcephaly as "a head size smaller than two standard deviations below the mean

³ It is not entirely clear why the special master decided the case on this basis. Arguably, the special master could have decided that the respondent proved that the injuries were caused by an unrelated condition rather than deciding that the petitioner failed to make a prima facie case. Nonetheless, we conclude that the decision is rationally based upon a consideration of the entire record.

for a child of the same sex and age.”⁴ Order at 6. Two standard deviations from the mean is approximately at the 2.5 percentile. Thus, because Maggie was in the second percentile at birth, she was microcephalic prior to the vaccine. Petitioners contend that the special master arbitrarily chose the strictest definition of “microcephaly” for which testimony was reached.

Each of the experts that testified in this case acknowledged that this definition was accepted by the medical profession. Both Dr. Slater and Dr. Evans testified that there was no uniformly accepted definition of microcephaly. Dr. Slater cited three medical textbooks—two of which defined microcephaly as a head size smaller than two standard deviations from the mean and one defined it as three standard deviations from the mean. When asked about Maggie’s condition prior to the vaccination, Dr. Slater testified that “[s]omething was clearly happening to the child before. Whether it was clear-cut secondary microcephaly depends on whether we are going to go with two or three standard deviations.” Tr. at 179-80. Dr. Evans defined microcephaly as a head size at or below the second percentile. He testified, however, that a common definition in the field was a head size more than two standard deviations from the mean. Dr. Kitts also testified that the definition of microcephaly is a head size that is more than two standard deviations from the mean and that this was the gen-

⁴ In finding that Maggie had a preexisting injury, the special master also relied on the discharge statement made by Maggie’s treating physicians following her August 1975 hospitalization. The statement that “children with microcephaly and some brain damage [are] unusually susceptible to this vaccine” is a clear indication that these doctors considered Maggie to be microcephalic prior to the vaccination.

erally accepted definition. Hence, the special master’s conclusion that a head size smaller than two standard deviations from the mean is the most commonly accepted definition of microcephaly is consistent with the expert testimony in the record.⁵

Because Maggie’s preexisting injury precluded the vaccination from being the cause of the encephalopathy, the special master proceeded to address the issue of whether her preexisting injury was significantly aggravated by the vaccination. The Vaccine Act defines “significant aggravation” as “any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.” 42 U.S.C.A. § 300aa-33(4). This court has devised a four-step evaluation, see *Misasi v. Secretary of HHS*, 23 Cl. Ct. 322, 324 (1991), which the special master applied to determine that the DPT vaccination did not significantly aggravate the preexisting microcephaly. In *Misasi*, this court held:

To evaluate whether an individual suffered a significant aggravation of a particular condition, it is necessary to (1) assess the individual’s condition prior to administration of the vaccine, i.e., evaluate the nature and extent of the individual’s pre-existing condition, (2) assess the individual’s current condition after the administration of the vaccine, (3) predict the individual’s

⁵ Both Drs. Kitts and Slater testified that it would take several weeks for a brain injury to cause a person’s head size to fall off the growth chart. Thus, the fact that Maggie’s head size was below the second percentile on August 20, 1975 would mean that she was microcephalic prior to the vaccination unless the most narrow definition, three standard deviations from the mean, were adopted.

condition had the vaccine not been administered, and (4) compare the individual's current condition with the predicted condition had the vaccine not been administered.

Misasi, 23 Cl. Ct. at 324.

The special master found that prior to the DPT vaccination, Maggie was microcephalic even though she showed few signs of having neurological problems. He found that she is currently severely mentally and physically disabled.

In his prediction of what Maggie's condition would have been if she had not received the vaccine, the special master concluded (1) that there was a greater than 90% likelihood that she would have been mentally retarded; (2) that the hip dislocations and subluxations were congenital; and (3) that she might have developed cerebral palsy. Each of these conclusions is supported by expert testimony and medical literature.*

In reaching the critical issue, whether it was more likely than not that the current condition was significantly worse than the predicted condition, the special master determined that it was necessary to focus on the events occurring in close temporal relationship with the vaccination. Since petitioner pursued this case as a table case, the first manifestation of the significant aggravation must have occurred within the time period after the vaccine administration set forth in the Vaccine Injury Table. 42 U.S.C.A. § 300aa-11(c)(1)(C)(i).

* Petitioner contends that the hip dislocations and subluxations were caused by her cerebral palsy. Even if this were true, it would be irrelevant for purposes of this action because the special master concluded that the cerebral palsy was not caused or aggravated by the DPT vaccination.

The special master concluded that the two manifestations of complications resulting from the vaccine—projectile vomiting and the seizures—were insufficient to show that Maggie's condition deteriorated as a result of the vaccination. He considered the projectile vomiting to be inconclusive because it had become a chronic problem associated with the excess accumulation of mucus. Accordingly, there was no reason to believe that it was uniquely related to the vaccine. Furthermore, the special master concluded that the seizures, although perhaps immediately secondary to the vaccination, were not an indication that the vaccination resulted in permanent neurological damage. There is simply no evidence that these transient seizures were a sign of permanent brain damage.

Moreover, there was testimony suggesting that Maggie's entire clinical history is typical for a person with a condition similar to Maggie's who did not have vaccine complications. Dr. Evans found her clinical course to be "typical for any other child that had cerebral palsy, microcephaly, mental retardation and epilepsy" without any DPT complications. Tr. at 227. Based upon all evidence in the record, we conclude the special master's decision, supported by Dr. Evans' testimony, was not arbitrary.

VII

Petitioner's objections to the special master's decision was overruled. The Clerk shall enter judgment for respondent in accordance with the special master's August 16, 1991 decision.

/s/ James T. Turner
JAMES T. TURNER
Judge

APPENDIX C

IN THE UNITED STATES CLAIMS COURT
OFFICE OF THE SPECIAL MASTERS

No. 90-692V

MARGARET WHITECOTTON, by her
next friends, KAY WHITECOTTON and
MICHAEL WHITECOTTON, PETITIONERS

v.

SECRETARY OF THE DEPT. OF HEALTH AND
HUMAN SERVICES, RESPONDENT

[Filed Aug. 16, 1991]

DECISION

BAIRD, Special Master

Petitioners seek compensation under the National Vaccine Injury Compensation Program¹ [hereinafter

¹ The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, as amended, 42 U.S.C.A. § 300aa-1 et seq. (West Supp. 1991). For convenience, individual sections of the Act will be cited herein without reference to 42 U.S.C.A. § 300aa.

the Program or the Act] for injury to their minor daughter Margaret Whitecotton (hereinafter "Maggie") allegedly resulting from a DPT (diphtheria, pertussis, and tetanus) vaccine administration on August 18, 1975.

Respondent filed a report which denies that petitioners are entitled to an award of compensation under the Program and asserts that Maggie's present condition is a result of a factor unrelated to the DPT vaccination, namely, chronic organic brain syndrome, a factor which preexisted the administration of the DPT vaccine.

A hearing limited to the issue of entitlement was held in Indianapolis, Indiana, on June 4, 1991.

THE STATUTORY SCHEME

Under the Act, there are two separate means of establishing entitlement to compensation. If an injury listed on the Vaccine Injury Table found at 42 U.S.C. § 300aa-14(a) (hereinafter "Table") occurred or was significantly aggravated within the time period prescribed in the Table, then a qualified petitioner is entitled to compensation unless there is a preponderance of evidence that the injury or aggravation was due to factors unrelated to the administration of the vaccine. Compensation may also be awarded for injuries not listed on the Table or which are listed but occurred outside the time limits of the Table, but entitlement in such cases is dependent upon proof by a preponderance of evidence that the vaccine actually caused the injury complained of. In either case, the residual effects must have persisted for at

least six months, and unreimbursable expenses in excess of \$1,000 must have been incurred as a result of the injury.

Petitioners have pursued their claim as a Table case. The petition alleged that Maggie suffered an encephalopathy and the onset of a seizure disorder² within three days following the administration of the DPT vaccine. Both "encephalopathy (or encephalitis)" and "residual seizure disorder" are Table-listed injuries for the DPT vaccine if the first symptom or manifestation of onset thereof appeared within three days following vaccination. Additional requirements for a residual seizure disorder are set out in § 14(b)(2) of the Act: The petitioner must not have suffered a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102° before the first seizure or convulsion following the administration of the vaccine and, within one year after the administration of the vaccine, two or more seizures or convulsions unaccompanied by fever or accompanied by a fever of less than 102° must have occurred.

² Actually, the petition does not allege that Maggie suffers from a Table residual seizure disorder. It alleges that Maggie suffers from a "post-vaccine encephalopathy that presented with seizures twenty-four hours after the vaccination." Petition at para. 5. In their opening statement at the hearing, however, petitioners argued, based on comments the court made at an early off-the-record status conference, that a Table residual seizure disorder did exist and moved for summary judgment on that issue. The motion was denied, but the court considered the issue of whether a Table residual seizure disorder existed to be before the court.

DISCUSSION

a. Table residual seizure disorder

It is undisputed that Maggie had a series of clonic seizures on August 19, 1975, and that her temperature was below 102° at the time. Based on the testimony of Maggie's mother, the court also considers it more likely than not that Maggie had similar seizures on the evening of August 18. This is sufficient to allow³ a finding that Maggie suffered the onset of a Table residual seizure disorder if she did not have and seizures prior to August 18, 1975, and the residual effects of the seizures recorded on August 19 continued for at least six months.⁴ There is some question in the record, however, as to each of those elements.

The possibility of prior seizures is raised in a note in the hospital records of August 20, 1975, wherein

³ Section 14(b)(2) provides that a petitioner "may"—not "shall"—be considered to have suffered a residual seizure disorder if the conditions of the section are met. This means that there can be no finding of a Table residual seizure disorder unless those conditions are met, but it does not compel a finding of such an injury if they are.

⁴ This conclusion is based on a literal reading of § 14(b)-(2)(B). Congress may have intended, however, that seizures occurring during the Table period should be considered as a unit and that the Table requirement is not satisfied unless at least one additional seizure with a temperature of less than 102° occurs outside the Table period and more than six months after the vaccination. This would be consistent with the requirement that the residual effects or complications continue for at least six months—the residual effects of a seizure disorder being more seizures.

the treating physician, Dr. Stanley Wissman, recorded his impression as follows: "Post-immunization seizures, [with] possible seizures earlier (leg jerks?)."⁵ Considering the testimony of Maggie's mother concerning those jerks and the testimony of the expert witnesses with respect thereto, the court is of the opinion that it is more likely than not that the leg jerking which occurred prior to August 18, 1975, was benign myoclonic sleep jerking and not seizure activity. Therefore, there is not a preponderance of evidence that Maggie had seizures prior to receiving the DPT shot on August 18.

Maggie did not have additional seizures for a considerable period of time after August 19, 1975. She became very still, flaccid, and pale on the evening of February 24, 1976, and, because of her prior seizures, was hospitalized for 10 days with the suspicion of possible seizures. However, an EEG taken on the day after admission was normal and she had no seizures while in the hospital. This led the treating personnel to conclude that she "probably had acute episodes of upper airway obstruction by large amounts of mucus and tenacious sputum."⁶ In January 1977, Maggie developed a fever of about 104° in connection with an upper respiratory infection and had what was diagnosed as a febrile convulsion.

An episode similar to the February 1976 episode occurred on August 28, 1979. Maggie suddenly went limp and became dusky and her eyes were rolling. Her mother took her to the emergency room where she threw up mucus on several occasions. She was admitted to the hospital for observation, but did not

⁵ Exhibit F to petition (Ex.) at 8.

⁶ Ex. H-3 at 2.

have any further problems. A chest x-ray suggested pneumonia in the left lung. She was given medication for pneumonitis and discharged. It was thought that her initial problem had probably been choking secondary to mucus in the throat.

Maggie had a grand mal seizure on March 21, 1980, the day after receiving a DT (diphtheria and tetanus) shot. She was taken to the hospital, where her temperature was recorded at 102°. Because she had a high leukocyte count, she was put on ampicillin. She was also given phenobarbital. That was the only time Maggie has been given anti-seizure medication. According to Mrs. Whitecotton, Maggie had focal seizures when she was in the early school grades, but she has not had any seizures in recent years. Gerald E. Slater, M.D.,⁷ the pediatric neurologist who testified for the petitioners was unable to state to a reasonable degree of medical certainty that Maggie suffers from a Table residual seizure disorder. Under examination by the court, he referred to her seizures following the vaccination as "transient" and to her subsequent seizure history as "questionable."⁸

Based on the clinical history and on the expert testimony, the court is unable to conclude that Maggie "suffered the residual effects or complications of [a seizure disorder] for more than six months after the administration of the vaccine," § 11(c)(1)(D)(i), even though she had more than two seizures unaccompanied by fever or accompanied by a fever of less

⁷ For the past two years, Dr. Slater has practiced both pediatrics and pediatric neurology in Glenwood Springs, Colorado. Between 1978 and 1989, he was a staff pediatric neurologist at the University of Minnesota.

⁸ Tr. at 191.

than 102° in the 48 hours following the vaccination. Further, the evidence is clear that she does not presently have a compensable residual seizure disorder.

b. Table encephalopathy

1. As an original injury

It was the opinion of the physicians who treated Maggie during her hospitalization in August 1975 that she had suffered a post-immunization encephalopathy. The discharge diagnosis read: "(1) Microcephaly. (2) Postimmunization encephalopathy with seizures."⁹ The discharge summary went on to state:

It was thought that the patient's seizures were most likely secondary to the pertussis vaccine which she had received earlier in the day. It was Dr. Drew's feeling that children with microcephaly and some brain damage were unusually susceptible to this vaccine. It was decided to not start this child on any anticonvulsive medications at this time. The child will be followed by Dr. Drew in his office for any further seizure difficulty or any other evidence of CNS dysfunction associated with the microcephaly.¹⁰

It is reasonable to infer from the discharge diagnosis and this statement that at least some of the treating physicians (1) considered Maggie to be microcephalic; (2) thought that she might have pre-existing brain damage; (3) considered her seizures to have been immediately secondary to the DPT vaccine but ultimately evidence of CNS dysfunction as-

⁹ Ex. F at 1.

¹⁰ Ex. F at 1-2.

sociated with microcephaly; (4) thought that her seizures might prove to be transient; and (5) were more concerned about her microcephaly—than about the post-immunization encephalopathy—as a potential cause of further CNS dysfunction.

When Maggie became microcephalic and the significance thereof—as contrasted to the significance of any damage related to the vaccination—were the primary points addressed by the expert witnesses. Dr. Slater did not define "microcephaly" but pointed out that there is no uniformly accepted definition of the term in the medical community. He cited three sources, two of which defined the term as more than two standard deviations below the mean, and one of which defined it as more than three standard deviations below the mean. Owen B. Evans, Jr., M.D.,¹¹ who testified for the respondent, did define the term and explained the significance of small head size:

These height, weight and head circumference measurements are used as screening tools for clinicians, nurses and others to identify patients at risk and who are low in weight, who are short in height, who have small heads, . . .

You will notice that some of them only go down to the fifth percentile. That is, many people believe that if somebody is below the fifth percentile they are very suspect and should be referred for further evaluations. Other authors believe the third percentile is a reasonable cut-

¹¹ Dr. Evans, who is board certified in pediatrics and pediatric neurology, is a professor in and chairman of the Department of Pediatrics and chief of the Division of Pediatric Neurology at University of Mississippi Medical Center, Jackson, Mississippi.

off for very suspect people. Others believe that two standard deviations, and yet another group will say the second percentile.

The point is that somebody with a small head when compared with the normal population is very much at risk of having developmental disabilities.

Now, the two standard deviations is going to fit . . . between the second percentile and the third percentile because it is about 2.5 percentile.

My definition of microcephaly is someone who is at the second percentile or less. If it is just below it or on it or what have you, that is a small head. . . .¹²

Having reviewed the sources cited at the hearing and consulted another source which has been cited previously by this court,¹³ the court adopts what it finds to be the most commonly accepted definition of microcephaly, namely, a head size smaller than two standard deviations below the mean for a child of the same sex and age. By that definition, as pointed out by Dr. Evans, a child whose head size is at the second percentile is microcephalic, since the cutoff for two standard deviations is above the second percentile.¹⁴

Applying this definition to the facts presented in this record, the court finds that Maggie was at least

¹² Tr. at 243-44.

¹³ Gerald M. Fenichel, *Clinical Pediatric Neurology* 369 (1988).

¹⁴ Dr. Evans cited the following sources, which support his testimony: Behrman & Vaughan, *Nelson Textbook of Pediatrics* 26 (13th ed. 1987); G. Kimble, *How to Use Statistics* 124 (1978). Dr. Slater acknowledged that the Behrman and Vaughan text is authoritative.

borderline microcephalic at birth and that she was clearly microcephalic by the time she received her third DPT shot on August 18, 1975. Maggie's head size at birth was 12.5 in.,¹⁵ which converts to 31.75 cm. on her growth record.¹⁶ Both Dr. Slater and Dr. Evans testified that this was right at the second percentile. Her head size stayed practically on the second percentile curve through three months of age, but dropped below that curve by August 20, the date of her hospitalization. This was noted in the discharge summary, "OFC was 37 cms., which is below two standard deviations from the norm,"¹⁷ and accounts for the diagnosis of microcephaly.¹⁸

In the succeeding months, Maggie's head growth fell further behind the norm for a girl of her age. Since the size of the head in a child is indicative of the size of the brain, the court is persuaded by this evidence and by the testimony of the neurologists that Maggie had suffered an encephalopathy sometime prior to the administration of the DPT vaccine on August 18, 1975. Dr. Slater acknowledged on several occasions in his testimony that "[s]omething was clearly happening to the child before [the DPT shot]. Whether it was clear cut secondary microcephaly depends on whether we are going to go with two or

¹⁵ Ex. B at 11.

¹⁶ Ex. C at 5.

¹⁷ Ex. F at 1. The measurement appears to have been taken on August 20. Ex. F at 5.

¹⁸ A second head measurement taken during the hospitalization was 36.5 cm. Ex. F at 7. If this measurement was accurate, then Maggie's head may not have grown at all since it was measured a month earlier.

three standard deviations.”¹⁹ In his report filed prior to the hearing, Dr. Slater stated:

It is the growth of the brain which promotes the growth of the skull. Her recorded head circumferences would indicate that her brain grew along its normal curve, albeit small, through the first three months of life. She then suffered impaired brain growth, and her head circumference fell off its normal curve. This is termed secondary microcephaly, and *implies a post-partum injury to the brain, at or near three months of age.*” (Emphasis added.)²⁰

It was Dr. Evans opinion that Maggie suffered brain injury prior to birth, as evidenced by her microcephaly. Whether the injury occurred prior to birth or thereafter, the preponderance of evidence indicates that Maggie was already encephalopathic prior to August 18, 1975. Her original encephalopathy was not a Table injury which followed the August 18 DPT shot.

2. As a significant aggravation of a preexisting injury

The petitioners did not allege that a preexisting encephalopathy was significantly aggravated within three days of the August 18, 1975 DPT vaccination,

¹⁹ Tr. at 179-80. See also Tr. at 187 and 201.

²⁰ Ex. L at 1-2. In his testimony, Dr. Slater left the door open to an earlier injury date. He stated that it would take from several weeks to several months for head trauma to result in microcephaly. He also stated that there was nothing in Maggie's head growth chart inconsistent with an injury late in gestation or during the perinatal or neonatal periods.

but in light of the record and the court's findings on the injuries which were alleged, consideration must be given to the question of whether Maggie's preexisting encephalopathy was significantly aggravated during that period. If it were significantly aggravated, then that would give rise to a presumption of entitlement to compensation.

The term “significant aggravation” is defined in § 33(4) of the Act as “any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.” The concept of significant aggravation is discussed in the legislative history as follows:

The committee has included significant aggravation in the Table in order not to exclude serious cases of illness because of possible minor events in the person's past medical history. This provision does not include compensation for conditions which might legitimately be described as pre-existing (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), but is meant to encompass serious deterioration (e.g., a child with monthly seizures who, after vaccination, has seizures on a daily basis). The Committee also intends that the time periods set forth in the Table apply to the significant aggravation in order for causation to be deemed to exist (e.g., a significant deterioration of a seizure disorder after DPT vaccination must first become manifest within three days of the vaccination).

H. R. Rep. 908, 99th Cong., 2nd Sess. Pt. 1 at 15-16, reprinted in U.S. Code Cong. & Admin. News 6344, 6356-57.

It has been held by this court that

To evaluate whether an individual suffered a significant aggravation of a particular condition, it is necessary to (1) assess the individual's condition prior to administration of the vaccine, *i.e.*, evaluate the nature and extent of the individual's pre-existing condition, (2) assess the individual's current condition after the administration of the vaccine, (3) predict the individual's condition had the vaccine not been administered, and (4) compare the individual's current condition with the predicted condition had the vaccine not been administered.

Misasi v. Secretary of HHS, No. 90-400V, slip op. at 3-4 (Cl. Ct. June 7, 1991). Each of these elements will be addressed in turn.

(1) Condition prior to the administration of the vaccine

Prior to the August 18 shot, Maggie was microcephalic. Beyond that, there were only some hints that Maggie might have neurologic complications. For example, she first rolled over from her stomach to her back at two weeks of age, which is very early. Dr. Evans testified that early rolling over is usually associated with spasticity, but there is no evidence of the observation of early spasticity in the records,²¹ and the photographs introduced at the hearing²² do

²¹ Maggie's early pediatric records are no longer available. All that exists is a letter from an associate of her pediatrician which indicates that Maggie was "seen at 3 weeks, 6 weeks, 2 months, 3 months and examinations were normal." Ex. D.

²² Ex. O-1 through O-9.

not show obvious signs of spasticity, so the significance of the early rolling over is questionable. D. S. Hwang, M.D., who was Maggie's treating physician at the time of her 1979 hospitalization, noted that she "has had difficulty swallowing since birth."²³ Mrs. Whitecotton denied the accuracy of that note, but the court considers it credible. Dr. Evans testified that "children with cerebral palsy and mental retardation often present with feeding difficulties because of the poor coordination of all their musculature, including that of sucking and swallowing."²⁴

(2) Current condition

Currently, Maggie is severely disabled both mentally and physically. She has cerebral palsy and has required surgery for hip and joint problems. She is nonambulatory. Her vocabulary is very limited. While she is able to provide some assistance in dressing, she is, for all practical purposes, totally dependent on others for her needs.

(3) Prediction of condition had the vaccine not been administered

The fact that there was little evidence of complications of microcephaly prior to August 18, 1975, does not mean that Maggie would have developed normally. It is not unusual that a neurological problem does not become evident until the central nervous system of an infant or child matures to the point where developmental milestones are missed or delayed. Hypertonicity generally develops gradually.

²³ Ex. H-12 at 3.

²⁴ Tr. at 209.

Ellen Louise Kitts, M.D.,²⁵ testified on behalf of the petitioners. She acknowledged that cerebral palsy typically becomes evident between six months and one year of age. Mental retardation may not become evident until much later. Based on her microcephaly alone, the court is able to predict with a high degree of certainty that Maggie would have been mentally retarded even if the DPT vaccine had not been administered to her on August 18, 1975. Dr. Menkes states in his textbook that nearly 100% of microcephalic children are mentally retarded.²⁶ Dr. Fenichel states that "almost every individual with microcephaly is mentally retarded."²⁷ Dr. Evans testified that only about 7.5% of microcephalics have normal intelligence. Thus, there was a greater than 90% likelihood that Maggie would have been mentally retarded based on her microcephaly alone.

The court is also able to predict with a high degree of certainty that Maggie would have experienced the hip dislocations and subluxations which she has experienced, absent the DPT shot. These problems are consistently referred to in the records as congenital in nature, and there is no basis for concluding that they are not.

The evidence relating to Maggie's cerebral palsy is not as clear. Both Dr. Slater and Dr. Evans agreed

²⁵ Dr. Kitts is a physician who specializes in pediatric physical medicine and rehabilitation. She is board certified in both pediatrics and physical medicine and rehabilitation. She resides in Wheeling, West Virginia, where she serves as medical director of the Easter Seal Rehabilitation Center.

²⁶ John H. Menkes, *Textbook of Child Neurology* 247 (4th ed. 1990).

²⁷ Gerald M. Fenichel, *supra*, n.13.

that, according to the literature, in most cases the etiology of cerebral palsy is never determined. However, Dr. Slater testified that mental retardation is associated with microcephaly, but that gross motor problems are not, while Dr. Evans testified that both mental retardation and motor impairments—including cerebral palsy—are typically associated with microcephaly. It appears from reviewing other sources²⁸ that cerebral palsy may result from primary or secondary microcephaly and that it always follows perinatal brain injuries. Thus, it is reasonable to conclude that Maggie's cerebral palsy may have occurred without any involvement of the DPT vaccine and that there is no way to know for certain whether the DPT vaccine caused or aggravated it.

- (4) Comparison of current condition with predicted condition had the vaccine not been administered

In conducting this aspect of the analysis, it is both necessary and appropriate to focus on the events which occurred in close temporal relationship to the vaccination to see what light they shed on the issue. It is necessary in a Table case because, in order to find a Table aggravation, the Act requires that the aggravation become evident during the Table period. It is appropriate in all cases because the timing of the onset of deterioration in condition following a vaccination bears on the issue of causation.

Maggie had seizures following the vaccination. Seizures are sometimes indicative of ongoing brain damage, but not necessarily so. The treating physi-

²⁸ Gerald M. Fenichel, *supra*, n. 13, at 370-72; John H. Menkes, *supra*, n. 26 at 245-47.

cians diagnosed a "postimmunization encephalopathy with seizures," so they must have associated the seizure activity with at least an acute encephalopathy. Mrs. Whitecotton testified that Maggie projectile vomited while in the hospital following the vaccination. Projectile vomiting is sometimes associated with the brain swelling which may accompany encephalopathy, so this is additional evidence that an encephalopathy may have been occurring at that time. However, Mrs. Whitecotton testified further that projectile vomiting became a chronic problem associated with the excess accumulation of mucus, so its significance is uncertain. She never mentioned the problem to Maggie's doctors.

Other than these symptoms, there is no evidence that Maggie suffered permanent neurological damage which significantly aggravated her preexisting condition in close temporal relationship to the vaccination. The discharge diagnosis included the following physical examination results:

The HEENT examination appeared to be normal. The remainder of the physical examination was unremarkable. Neurological examination revealed the patient to be alert, follow objects with her eyes past midline, trying to reach for the objects with both hands. Motor examination revealed good activity in all motor groups. The tone, though difficult to assess, appeared to be normal. Muscle stretch reflexes were normoactive and equal bilaterally.²⁹

There is no indication in this report that Maggie's neurological condition had deteriorated or was deteriorating.

²⁹ Ex. F at 1.

Mrs. Whitecotton testified that Maggie lost some developmental milestones following the shot—she became slouchy and lost the ability to raise her feet up in front of her hands—and that other milestones became "scattered."³⁰ She also testified that Maggie became fretful after the shot. However, there is no evidence of any of this in the medical records. The pediatric records are unavailable. When Maggie was hospitalized in February 1976, it was noted that she had started gagging herself and vomiting for attention (she would stop when she was picked up) four months earlier, at the age of six months. This activity had ceased two months prior to admission. Her growth had been slow, but it had never stopped. She began sitting at four to five months of age and was now able to crawl and, to some extent, pull herself up. There was no head lag. She grasped, tracked, supported her weight, and supported herself in a prone position. She was thought to be somewhat hypertonic intermittently. The weight of the evidence is that there was no dramatic change in Maggie's condition following the DPT shot. Her development was slow but sure, and the onset of hypertonicity was gradual. There is nothing to distinguish this case from what would reasonably have been expected considering her microcephaly.

It was Dr. Kitt's opinion that all of Maggie's problems flow from a single source. "[T]here was a brain injury that caused the microcephaly that caused the seizures that caused the cerebral palsy."³¹ "It is a single brain injury that caused all of the above, and microcephaly is one of the manifestations of that

³⁰ Tr. at 26.

³¹ Tr. at 118.

brain injury.”³² Dr. Kitts attributed all of Maggie’s problems to the DPT vaccine, but, in light of the fact that the microcephaly predated the DPT vaccination, that is not a reasonable conclusion.

Dr. Evans also attributed all of Maggie’s problems to a single source—prenatal chronic organic brain syndrome. He found her clinical course to be typical “for any other child that had cerebral palsy, microcephaly, mental retardation and epilepsy” without any DPT complications.³³ He stated that 36% of the infants who are going to develop neurologic disorders appear neurologically normal at four months of age. Dr. Kitts testified that cerebral palsy frequently does not manifest itself prior to six months of age.

It appears from the record as a whole that there was a single brain injury that caused all of Maggie’s problems. Maggie was born with a brain defect, and there was nothing that occurred in temporal relationship to the DPT vaccination which indicates that it is more likely than not that the vaccine permanently aggravated her condition. It may have caused a temporary encephalopathy evidenced by transient seizure activity, but the seizures did not continue and there was no dramatic turn for the worse in her condition indicating a permanent aggravation of her brain disorder. Nor were there clearly any acute signs of encephalopathy other than the seizures. As she matured neurologically, the complications of whatever caused her microcephaly gradually manifested themselves, just as they do in a typical case involving congenital brain damage.³⁴ Thus, there is no basis for

³² Tr. at 119.

³³ Tr. at 227.

³⁴ Dr. Kitts testified that cerebral palsy frequently does not manifest itself prior to six months of age.

implicating the vaccine as the cause of any aspect of her present condition.

FINDINGS OF FACT

The following findings of fact are supported by a preponderance of the evidence:

1. Maggie Whitecotton was born on April 22, 1975, with a brain disorder evidenced by microcephaly which became more pronounced by the age of four months.

2. On August 18, 1975, the DPT vaccine was administered to Maggie in Indiana.

3. Maggie suffered transient seizure activity within three days following the administration of the DPT vaccine, the residual effects or complications of which did not continue for six months.

4. Maggie did not suffer a permanent encephalopathy within three days following the said administration of DPT vaccine.

5. No significant aggravation of Maggie’s underlying brain disorder was manifested within three days following the said administration of the DPT vaccine.

6. The DPT vaccine did not cause a significant aggravation of Maggie’s underlying condition.

CONCLUSION OF LAW

Petitioners are not entitled to an award of compensation under the Program.

In the absence of a motion for review filed pursuant to RUSCC Appendix J, the clerk of the court is directed to enter judgment in accordance herewith.

/s/ Paul T. Baird
PAUL T. BAIRD
Special Master

APPENDIX D

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 92-5083

MARGARET WHITECOTTON, by her next friends,
KAY WHITECOTTON and MICHAEL WHITECOTTON,
PETITIONERS-APPELLANTS

v.

SECRETARY OF THE DEPARTMENT OF
HEALTH AND HUMAN SERVICES,
RESPONDENT-APPELLEE

[Filed Apr. 29, 1994]

ORDER

A combined petition for rehearing and suggestion for rehearing in banc having been filed by the APPELLEE, and a response thereto having been invited by the court and filed by the APPELLANT, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the suggestion for rehearing in banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the suggestion for rehearing in banc be, and the same hereby is, DECLINED.

The mandate of the court will issue on May 6, 1994.

Circuit Judge NIES would rehear the appeal.

FOR THE COURT,
FRANCIS X. GINDHART
Clerk

By /s/ Diane M. Frye
DIANE M. FRYE
Chief Deputy Clerk

Dated: April 29, 1994

cc: JOHN S. CAPPER, IV
KAREN P. HEWITT

WHITECOTTON V HHS, 92-5083
(CLM—90-692 V)